

MagSense[™] Technology

Early detection of cancer through targeted imaging

ASX:IBX

www.imagionbiosystems.com

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IMAGION BIOSYSTEMS AT-A-GLANCE



New medical imaging technologies for the early detection of cancer

Imagion Biosystems ASX:IBX

Australian Medical Device Company developing bio-safe medical imaging technologies.

Market cap: ~\$14.8 million Net cash at 31 Dec 2019: \$3.4M Listed on the ASX: June 2017 R&D operations: San Diego Registered office: Melbourne

Recent Milestones: February 2020 Commenced GMP manufacturing

October 2019 Scientific Advisory Board (SAB) established

<u>July 2019</u> Received "*Breakthrough Device*" designation by U.S. FDA

- Innovative medical imaging using magnetic nanoparticles to identify and stage cancer early
- Proprietary MagSense™ technology is non-invasive and provides more specific & sensitive detection for cancer than current imaging technologies
- Multiple commercial opportunities:
 - Proprietary MagSense[™] imaging technology
 - Magnetic Resonance Imaging (MRI) contrast agent
 - Therapy and/or drug delivery
- MagSense[™] technology complements existing imaging and is more cost effective than many existing imaging technologies
- First-in-human studies on-track for 2020 targeting metastatic breast cancer



Patents are already issued, or are pending, in all the major markets, making the lions share of the global markets available for commercialization. *Patents are valid through 2029.*

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A GROWING GLOBAL HEALTH PROBLEM

1 in 3 people are affected by cancer

\$100B CANCER DIAGNOSTICS MARKET

\$30.000 \$26,044 \$25,000 \$20.136 \$20,000 Millions (USD) \$15,541 \$15,000 \$9,632 \$7,246 \$8.850 \$10,000 \$5.908 \$3,055 \$4,583 \$5,000 Breast Warian ancreatic Lidney liver prostate colorectal LUNB

Each year cancer kills 9 million people

\$100B spent annually to diagnose or detect cancer, yet cancer continues to be a leading cause of mortality and morbidity



CLEAR UNMET MEDICAL NEED

All

50 years since last new imaging technology was introduced



X-RAY (MAMMOGRAPHY) 1913

- Best used for finding structural anomalies (e.g. broken bones), and chest X-rays
- Mammography used for screening for breast cancer
- Risks include exposure to carcinogenic ionizing radiation



ULTRASOUND 1956

- Inexpensive and fast method to look at human organs and areas of inflammation
- Used to guide needle biopsies and detect ovarian cancer
- Poor sensitivity to detecting tumors – tumours must be billions of cells in size



MAGNETIC RESONANCE (MRI) 1971

- Best for imaging soft tissue including ligaments, tendons, the brain, and many internal organs
- Used for detecting brain cancers
- Scans can be long and clostrophobic



COMPUTED TOMOGRAPHY (CT) 1972

- Better for imaging the lungs than MRI
- Scan times shorter than
 MRI
- Used in staging solid tumors, guiding biopsy
- Exposes patients to carcinogenic ionizing radiation



POSITRON EMISSION TOMOGRAPHY (PET) 1973

- Can be expensive and poorer resolution than MRI or CT
- Better sensitivity for identification of metastatic lesions
- Subject to significant off-target and high background signals
- Requires use of radioactive tracer exposing patients to radiation

"Despite technical advances in many areas of diagnostic radiology, the detection and imaging of human cancer remains poor."

Journal of Clinical Oncology, 2008 New Technologies for Human Cancer Imaging Vol 26 No 24

MEDICAL IMAGING BREAKTHROUGH

MagSense[™] Technology will transform cancer diagnosis

- Non-invasive a safe and non-surgical solution to detect cancer
- No radioactivity uses bio-safe magnetic nanoparticles to "tag" cancer cells
- **Platform technology** can be used for many cancers as well as other diseases, e.g. infection and cardiovascular
- **Proprietary** patent issued in most major global markets
- **Breakthrough** technical feasibility and safety profile vetted, designated as a "breakthrough device" by FDA
- **First indication** metastatic breast cancer, provides shortest path to commercialization
- First-in-human ready for clinical studies a catalyst for valuation and partnering







IMPROVING OUTCOMES

Better sensitivity could mean earlier detection

MagSense[™] technology is expected to have sensitivity comparable to PET without use of radioactivity, making it better for routine use in early detection and resulting in more successful treatments and patient outcomes.



^{*} Source: SEER Cancer statistics, National Cancer Institute,2013

"Early detection of many diseases, particularly cancers, is key to successful treatment."

Chemical Reviews 2015 Nanoparticles in Medicine Vol 115





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TRANSFORMATIVE FOR MEDICAL IMAGING

Designated by FDA as a "Breakthrough Device"

The MagSense[™] HER2 Metastatic Breast Cancer Test

- Works within current standard cancer diagnosis and staging protocols.
- Replaces current non-functional imaging such as MRI or ultrasound used to assess for enlarged lymph nodes but which cannot determine if tumor cells are present.
- Would eliminate unnecessary biopsies for patients that do not have metastatic spread to the lymph nodes.
- Would reduce incidence of lymphedema and associated morbidity.

The MagSense™ system and test has been designated by the FDA as a **Breakthrough Device** - reserved for products that provide for more effective treatment or diagnosis.





BROAD COMMERCIAL APPLICABILITY

Can be used for many types of cancer and at multiple stages of diagnosis



- Are bio-functionalized to ensure high specificity for targeting different types of cancers, or other diseases.
- Can be used at multiple stages including primary diagnosis, staging, and monitoring the effectiveness of therapy.
- Are compatible with Imagion's proprietary MagSense technology and with existing installed MRI systems as an MRI contrast agent.
- Uses known safe materials, including iron-oxide cores which are already cleared for multiple clinical uses including therapeutic applications.

MULTIPLE CLINICAL TARGETS



COMPELLING BUSINESS MODEL

Proprietary consumable drives growth & profitability

ONE INSTRUMENT



US\$500K Capital Sale

50% Gross Margin

MANY TESTS



HER2 Breast Cancer



Prostate Cancer



Lung Cancer

Ovarian

Cancer

US\$1,500 / Test

80% Gross Margin



PRINTER / INK REVENUE MODEL

35% capacity utilization A\$2.2 million annual revenue per instrument

Revenue through licensing/partnership fees Royalties or revenue share on tests

INVESTMENT RATIONALE



Strategic plan provides path to future products & shareholder value



STAGING BREAST CANCER

Reduce unnecessary surgery

\$700M

TUMOR DETECTION

Breast, prostate, lung & ovarian

\$7B

MRI CONTRAST

Safer alternative to current product, Gadolinium

>\$3B

TREATMENT MONITORING

Monitor tumor size and adjust treatment accordingly

>\$2B

Addressable Markets

DOCTORS OFFICE

Hand-held MagSense instrument

>\$14B

DETECTION & THERAPY

Provide both detection & delivery of therapy

>\$140B

MILESTONES AND VALUATION DRIVERS



Indicative development timeline and key inflection points*

Milestones Achieved in 2018-19

- Lead formulation identified
- ✓ Preclinical models validated
- ✓ Formulation pilot production
- ✓ Toxicity study successfully completed
- ✓ Clinical instrument design plan complete
- ✓ Pre-IDE submission to FDA
- ✓ "Breakthrough device" designation awarded by the FDA
- ✓ Scientific Advisory Board established to guide and de-risk activities

- First-in-human study in FY2020 study duration expected to be 3-6 months.
 - First human data key validation point, paves way for discussion with commercial partners.
- GMP manufacturing of nanoparticles for use in human study key driver of schedule.
- **FDA communication** for approval to commence study in process, breakthrough status ensures expedited communication.
- Clinical site contract discussions initiated; MD Anderson and additional sites under consideration.



2018 - 2019

* This development timeline is indicative only, and subject to change.

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SCIENTIFIC ADVISORY BOARD



Collective expertise in oncology, medical imaging, nanotechnology, clinical trial design



DR JOHN HAZLE SCIENTIFIC ADVISORY BOARD CHAIR

- Board certified in medical physics
- 30 years in pre-clinical & clinical imaging research
- Chairs Cancer Research at UT Graduate School of Biomedical Sciences



PROF LISA HORVARTH

- Director, Department of Medical Oncology, Chris O'Brien Lifehouse
- Head of Clinical Prostate Cancer Research, Garvan Institute of Medical Research



DR ROBERT IVKOV

 Expertise in radiation oncology and development and characterization of magnetic nanoparticles

World class scientific collaborations & partnerships:



Making Cancer History*





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GLOBAL CANCER TECHNOLOGY



PROF ANDREW SCOTT

- Director, Department of Molecular Imaging, Olivia Newton-John Cancer Research Institute
- Experience in pre-clinical development and first inhuman trials.



DR PAUL GRINT

- Expertise in commercialisation of molecules
- Over 20 years experience in biologics and small molecule R&D

EXPERIENCED BOARD & MANAGEMENT



Commercially focused team with deep industry & clinical experience



ROBERT PROULX CHAIRMAN & CEO

- Operationally oriented executive
- 25 years in life science & medical devices
- Product development & commercialization



OLIVER STEINBACH VP CLINICAL & REGULATORY AFFAIRS

 Over 20 years in pharmaceutical, diagnostics and medical devices



MICHAEL HARSH NON EXEC DIRECTOR

- Former CTO of GE Healthcare
- 35 years in medical imaging product development



DAVID LUDVIGSON NON EXEC DIRECTOR

- 35 years in pharma, medical devices
- Corporate strategy, M&A, & financing



BRONWYN LE GRICE NON EXEC DIRECTOR

 15 years in Australian commercial healthcare & technology markets



BRIAN CONN CFO

- CFO for early & growth stage biotech
- 25 years raising both public & private capital & M&A



MARIE ZHANG PHD VP R&D

- 20 years in drug development
- Leadership in early stage and startup founder



MARK VAN ASTEN NON EXEC DIRECTOR

- Strong track record in diagnostics & healthcare
- 25 commercializing diagnostic products



JOVANKA NAUMOSKA NON EXEC DIR & COSEC

 Australian attorney with expertise in regulatory compliance, governance & risk management

CAPITAL STRUCTURE

No debt, one class of common stock

Ordinary shares on issue	511.28M*	
Share price (26 Feb 2020)	0.029	
Average daily volume	7.2M	
Market capitalization (26 Feb 2020)	14.83M	
Net cash (31 Dec 2019)	\$3.4M	
Major Shareholders * (as of 26 Feb 2020)	Manhattan Scientifics Inc	12.5%
× ,	Drake Special Situations LLC	4.89%
	Kenneth James Baker	3.38%
	Kemper Shaw	2.89%
	Board of Regents Univ Texas	2.06%

Share price – Last 12 months



Management and Board hold 0.36 % of ordinary shares on issue. Does not include unvested ISO and Long-Term Incentive Plans, which allocates a total of 12,100,000 shares to the Key Management Group and a total of 3,450,000 shares to NEDs and employees, on vesting schedule or as performance rights.

INVESTMENT HIGHLIGHTS



LARGE OPPORTUNITY \$100B cancer diagnostic market Growing 7% annually Medical imaging commands largest share Huge medical need for early diagnosis

UNIQUE TECHNOLOGY

New form of medical imaging Molecularly specific & non-invasive More sensitive than current methods Protected by eight patents

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COMMERCIAL STRATEGY
\$2B initial market focus
Applies to many types of cancer
Printer-ink revenue model
Potential for therapeutics & research markets



READY TO ENTER THE CLINIC

Technical feasibility demonstrated

Safety profile of technology vetted

FDA "breakthrough device" designation

First-in-human data readout expected in 2020

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Appendix

HOW IT WORKS

Bio-safe magnetic nanoparticles are attracted to the tumor and detected



- Nanoparticles, specific for the cancer, bind to tumor cells.
- Nanoparticles demagnetize or "relax" after exposure to a low magnetic field.
- Nanoparticles attached to cancer cells "relax" more slowly than particles in circulation acting as a magnetic beacon.
- Ultra-sensitive detectors locate the presence of attached nanoparticles.

US Patent 9095270 - Detection, measurement, & imaging of cells such as cancer & other biological substances using targeted nanoparticle & magnetic properties thereof



PRE-CLINICAL RESEARCH

Product performance verified in pre-clinical models

SPECIFICITY

- In vitro cell based studies confirm specificity for HER2 expressing breast cancer cells.
- Animal studies confirm in vivo selectivity for HER2 expressing breast cancer tumours.

SENSITIVITY

- In vitro cell based studies indicate target level of sensitivity should be achievable.
- In vitro and in vivo animal studies indicate little nonspecific background.

SAFETY

• GLP-compliant toxicology and toxicokinetic study showed no adverse effects.







IMPROVING MRI DIAGNOSTIC UTILITY

Additional commercial opportunity as an MRI contrast agent

- MagSense[™] iron oxide nanoparticles generate T2* MRI contrast even at low concentrations.
- Targeted nanoparticles would change MRI from identifying a region of interest to imaging for specific tumor cells.
- MRI utility provides additional or alternative development path expanding and further de-risks venture investment. *
- Favorable commercialization path eliminates need to sell new instrumentation and leverages installed base of >5000 clinical MRI scanners.



MRI Contrast Agents -\$3B Annual Market

* Further development of the MRI contrast agent capabilities is not the current priority due to the more favorable regulatory environment for the MagSense technology as a medical device.

